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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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EXAMINER

ART UNIT	PAPER NUMBER
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DATE MAILED:

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/559,622

Applicant(s)
Ranganathan, R. et al.

Examiner
Joseph T. Woitach

Art Unit
1632



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Oct 27, 2000
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claims 1-21 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) approved b) disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) All b) Some* c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- | | |
|--|---|
| 15) Notice of References Cited (PTO-892) | 18) Interview Summary (PTO 413) Paper No. s |
| 16) Notice of Draftsperson's Patent Drawing Review (PTO-948) | 19) Notice of Informal Patent Application (PTO-152) |
| 17) Information Disclosure Statement(s) (PTO-1449) Paper No. s | 20) Other |

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DETAILED ACTION

This application is an original application files April 27, 2000, which claims benefit to 60/131,149, filed April 27, 1999.

Claim 16 as written is dependent on claim 85, however there is no claim 85 pending. For purposes of restriction and compact prosecution, claim 16 will be considered dependent on claim 15. Claims 1-21 are pending and currently under examination.

Election/Restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1, 3, 5 and 16, drawn to a substantially pure nucleic acid sequence encoding a serotonin-gated anion channel wherein the serotonin-gated anion channel is MOD-1, classified in class 536, subclass 23.1.
- II. Claim 2, 4 and 6, drawn to a substantially pure polypeptide, classified in class 530, subclass 350.
- III. Claim 7, drawn to an antibody that specifically binds to a serotonin-gated anion channel, classified in class 530, subclass 387.1.
- IV. Claim 8, drawn to a *C. elegans* strain having a mutant mod-1 gene, classified in class 800, subclass 8.

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- V. Claims 9 and 11, drawn to a method for identifying a compound that modulates the biological activity of a serotonin-gated anion channel comprising administering a test compound and assaying a modulation, classified in class 435, subclass 7.1.
- VI. Claim 10, drawn to a diagnostic probe for detecting conditions associated with a serotonin-gated anion channel response, cannot be classified because the nature of the probe is not clearly defined in the claim nor the specification.
- VII. Claim 12, drawn to a method for decreasing serotonin-gated anion channel function comprising administering an antisense RNA, classified in class 514, subclass 44.
- VIII. Claims 13, drawn to a method for decreasing serotonin-gated anion channel function comprising administering an antibody, classified in class 514, subclass 2.
- IX. Claim 14, drawn to a method to modulate serotonin-gated anion channel function comprising administering a nucleic acid vector, classified in class 514, subclass 44.
- X. Claim 15, drawn to a method of identifying a gene that is structurally related to a gene encoding a serotonin-gated anion channel comprising identifying a gene with a probe to a serotonin-gated anion channel or a product encoded by a serotonin-gated anion channel gene, and the product identified by this process, classified in class 435, subclass 6.
- XI. Claim 17, drawn to a transgenic animal that over-expresses a serotonin anion channel, classified in class 800, subclass 13.

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XII. Claim 18, drawn to a transgenic animal that under-expresses a serotonin anion channel, classified in class 800, subclass 13.

XIII. Claim 19, drawn to a transgenic animal that expresses a dominant negative serotonin anion channel classified in class 800, subclass 13.

The inventions are distinct, each from the other because of the following reasons:

Inventions I, II, III and IV are unrelated. Although there are no provisions under the section for "Relationship of Inventions" in MPEP 806.05 for inventive groups that are directed to different products, restriction is deemed to be proper because the products or methods appear to constitute patentably distinct inventions representing distinct inventions. In the instant case the nucleic acid is chemically and structurally different than a polypeptide and while an antibody is a polypeptide it has different biological activities than that of a serotonin anion channel. Further, a *C. elegans* contains polypeptides and nucleic acids (not antibodies) but differs because it is a living organism. The nucleic acid can be used as a probe to identify the expression levels by Northern blot analysis, the polypeptide can be used to generate antibodies specific to a serotonin anion channel, the antibodies can be used to identify a serotonin anion channel in a sample, and the *C. elegans* can be used for physiological studies.

Inventions XI-XIII are unrelated. Although there are no provisions under the section for "Relationship of Inventions" in MPEP 806.05 for inventive groups that are directed to different products, restriction is deemed to be proper because the products or methods appear to constitute patentably distinct inventions representing distinct inventions. In the instant case the different

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inventions encompass three different and distinct transgenic animals. The transgenic animal of group XI contains a construct that over-expresses a serotonin anion channel, group XII under-expresses a serotonin anion channel, and group XIII expresses a completely different dominant negative serotonin anion channel.

Inventions X and I are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the method of claim 15 uses a probe to identify a structurally related gene recited in claim 16 or a related polynucleotide of claims 1, 3 and 5, however the product of claim 16 can also be identified and cloned by functional assays. Further, the method of claim 15 may also identify gene which are homologous but which are not structurally similar.

Inventions I and VII, IX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product of group I can all be used as a probe in Northern blot analysis.

Inventions III and VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown. (1) the process for using the

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product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibody of III can be used to purify a serotonin anion channel from a cell extract sample.

Inventions V, VII, VIII, IX and X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions encompass six different and distinct methods. Each of the methods require different materials to practice and different method steps which all result in materially different effects/outcomes.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, and the search required for Group I is not required for Groups II-XIII, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently

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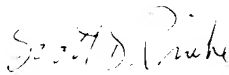
named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Woitach, whose telephone number is (703) 305-3732. The examiner can normally be reached on Monday through Friday from 8:00 to 4:30 (Eastern time).

If attempts to reach the examinee by telephone are unsuccessful, the examiner's supervisor, Karen Hauda, can be reached on (703) 305-6608.

An inquiry of a general nature or relating to the status of the application should be directed to Kay Pickney whose telephone number is (703) 305-3553.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.


SCOTT D. PRIEBE, PH.D.
PRIMARY EXAMINER

Joseph T. Woitach